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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,157	03/09/2004	Martin Oft	DX06022 US 01	4687

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,157	OFT ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/19/04 & 1/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election with traverse of Group V invention, claims 1-14, directed to SEQ ID NO:2, filed on 24 April 2006 is acknowledged. The traversal is on the ground(s) that, with respect to SEQ ID NO:2 and 4, they represent the amino acid sequences of human and mouse IL-23 p19, respectively, which are less than the ten sequences suggested as normally constituting a reasonable number for examination purposes according to MPEP, and that if the search and examination of all of the claims in an application can be made without serious burden, the examiner must examine them on the merits even though they include claims to independent inventions (MPEP). This is not found persuasive because the human and mouse IL-23 p19 are patentably distinct chemical entities as each has a unique sequence, and thus, they require separate search of the prior art. Further, the issue in question was a partial waiver of restriction practice to allow examination of up to ten sequences, which is not a requirement. This waiver was issued in 1996. Given the fact that since then, the size of the nucleic acid and protein databases that must be searched for each of the independent and distinct sequence claimed herein has been increased exponentially, it is now burdensome to search more than a single sequence in an application.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's preliminary amendment filed on 24 April 2006 is acknowledged and entered. Following the amendment, claims 15-18 are canceled, and claims 1, 4, 5, 8, 10 and 11 are amended.

Currently, claims 1-14 are pending and under consideration. The claims will be examined to the extent that they read on the elected sequence, SEQ ID NO:2.

Formal Matters:

Information Disclosure Statement

Applicant's IDSs submitted on 8/19/04 and 1/11/05 are acknowledged and has been considered. A signed copy is attached hereto.

Priority acknowledgement

This application claims benefit of U.S. provisional application No. 60/453,672, filed on 3/10/03, which is acknowledged.

Specification

The use of the trademarks have been noted in this application, for example, [0080] on page 24, and the first line on page 26, for example. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claims

Claims 4 and 10 are objected to for encompassing a non-elected subject matter, SEQ ID NO:4. The applicant is required to amend the claims to read only upon the elected invention.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite for the recitation of "*a* polypeptide of p19 (SEQ ID NO:2)" because it is unclear whether it means the entire sequence of the p19 of SEQ ID NO:2, or a random fragment of SEQ ID NO:2. Also, "*a* polypeptide" of SEQ ID NO:2 could be merely 2 amino acids, which is not sufficient to comprise an epitope (for antibody to bind). "*The* polypeptide of SEQ ID NO:2" is suggested. Claim 10 is similarly indefinite.

The remaining claims are included in this rejection because they are dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-10 and 12-14 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass "an antagonist of IL-23" (claims 1 and 8, for example), "a binding composition" for the polypeptide of p19 (claims 4 and 10, for example), or "a peptide mimetic of an antibody" (claims 6 and 12, part e), for example), which read on any or all functional equivalents of molecules without any structural limitation. Thus, the claims are drawn to a genus of molecules, which is defined only by functional limitation, and thus, encompasses extreme structural dissimilarity. For example, it can include antibodies, peptides, small chemical molecules. However, the specification merely discloses two antibodies to IL-23, anti-p40 and anti-p19, and the soluble IL-23R, and no other molecules meeting the limitation of the claims were ever identified or particularly described.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a functional characteristic, modulating or inhibiting tumor growth. There is no structural identification of any kind for the encompassed molecules. Thus, with the exception of the anti-p19 and anti-p40 antibodies, and the IL-23R, the skilled artisan cannot envision the detailed chemical structure of the encompassed "antagonist of IL-23", "a binding composition", or "a peptide mimetic" and therefore conception is not achieved regardless of the complexity or simplicity of the method of making a peptide or chemical molecule. Accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, in the instant case, only the anti-p19 antibody, the anti-p40 antibody, and the IL-23R, but not the full breadth of the claims ("an antagonist of IL-23", "a binding composition", or "a peptide mimetic of an antibody") meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7-9, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Carton et al., US 2003/0157105 A1.

Carton discloses anti-p40 Ig derived proteins (the abstract, and page 1, [0010]), and a method of using thereof for treating IL-12 related conditions, including treating malignant diseases such as, among others, colorectal carcinoma, pancreatic carcinoma, and malignant melanoma (page 18, [0150]). As such, the reference anticipates the present claims 1, 2, 7-9, 13 and 14. Note, although the present specification does not specify that anti-p40 antibody is an agonist or antagonist of IL-23, it is interpreted as that anti-p40 antibody is an antagonist of IL-23 because the specification states that "antagonist of IL-23 include, e.g., antibodies to IL-23, ..." (page 13, [0042]), and p40 is one of the two subunits of IL-23.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/6/06